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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,268	09/29/2003	Michael Fantuzzi	33503/US	3101

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DORSEY & WHITNEY, LLP
INTELLECTUAL PROPERTY DEPARTMENT
1400 Wewatta Street
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EXAMINER

KOSSON, ROSANNE

ART UNIT	PAPER NUMBER
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1652

NOTIFICATION DATE	DELIVERY MODE
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07/06/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/674,268	FANTUZZI, MICHAEL	
	Examiner	Art Unit	
	ROSANNE KOSSON	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15, 18-20, 22, 23, 32-34, 36-43 and 45-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 18-20, 22, 23, 32-34, 36-43 and 45-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/13/11</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's Response filed on June 13, 2011 has been received and entered. No claims have been amended or added. Claims 1-13, 16, 17, 21, 24-31, 35 and 44 have been canceled. Accordingly, claims 14, 15, 18-20, 22, 23, 32-34, 36-43 and 45-55 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph, Written Description

Claims 32, 42, 45, 52 and 54 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As discussed in the previous Office action, the aforementioned claims, except for claim 45, recite a composition that is a soft gel comprising about a 30% solution of coenzyme Q10 (co Q10) in limonene. Claim 45 recites a composition that is a soft gel comprising about a 25% solution of co Q10 in limonene. These limitations are not present in the application as filed, with or without about before the percentage, and are therefore new matter. Paragraphs 17 and 18 of the as-filed specification (which are the paragraphs cited by Applicant as providing support for the amended claims) provide support for the other ranges and concentrations recited in the amended claim set, as these paragraphs disclose the other concentrations that are the upper and lower limits of the ranges recited in the instant claim set. The concentrations in the specification may be combined to create new ranges. But, the aforementioned claims recite data points that are new, that are not present in

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these paragraphs, and that, as a result, may not be combined with other data points to create new ranges. THIS IS A NEW MATTER REJECTION. New matter is prohibited, and Applicants are required to cancel new matter from the claims (see MPEP 608.04).

Applicant asserts that the new data points are not new matter, because they are inherently present in the as-filed specification and because *ipsis verbis* support is not required. In reply, the new data points are not inherently present in the as-filed specification. A concentration range for the amount of co Q10 (coenzyme Q10) dissolved in the d-limonene does not provide support, even non *ipsis verbis*, for all of the individual values in that range. Values in that range that were not individually named at the time of filing were not recognized as having a particular significance, and these new values, to which some sort of significance is implied, may not be created post filing. As previously discussed, data points in the as-filed specification may be rearranged in amended claims, to make new ranges. But, new data points may not be added, as individual values or as the limits of ranges. Further, the new data points raise the question of why these new ranges are now being claimed. What has Applicant discovered since the application was filed? In view of the foregoing, the rejection of record is maintained.

Claim Rejections - 35 USC § 103

In view of the decision from the BPAI (Board of Patent Appeals and Interferences) in copending Application No. 10/953328 mailed on May 11, 2011, the obviousness rejection is withdrawn.

Double Patenting- Obviousness-type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

With respect to the non-statutory double patenting rejection(s) made in this Office action, note as follows. The use of the terminology “defined in 35 U.S.C. §154 to §156 and §173” in a terminal disclaimer can result in the terminal disclaimer being found improper. To address this, note that a proper terminal disclaimer need only disclaim the patent’s remaining “full statutory term” as defined in 35 U.S.C., without specifying 35 U.S.C. 154 and 173. This is so, because the “full statutory term” inherently is a statutorily defined item. Note that the above language corresponds to PTO/SB/25 (07-09) (reproduced at page 1400-120 in Revision 7 (July 2008) of the 8th edition of the MPEP), but the reference to 35 U.S.C. 154 and 173 has been deleted.

Accordingly, the following language would be deemed acceptable:

The owner*, _____, of _____ percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond

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the expiration date of the full statutory term of any patent granted on pending **reference** Application Number _____, filed on _____, and as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the **reference** application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said **reference** application, "as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application," in the event that: any such patent: granted on the pending **reference** application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Claims 14, 15, 18-20, 22, 23, 32-34, 36-43 and 45-55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 7,169,385. Although the conflicting claims are not identical, they are not patentably distinct from each other because each claim set is drawn to the same invention, a composition or nutraceutical formulation comprising a solution of co Q10 dissolved in limonene. Patented claims 3-5 and 15-25 recite that the composition is a caplet or soft gel capsule/caplet. The instant claims are broader than the patented claims, because the patented claims recite that the composition comprises carnitine as well. But, the instant specification discloses that the composition may further comprise carnitine as an additional therapeutic ingredient. See paragraphs 35 and 36. The additional limitations recited in the instant and in the patented claims, the concentration ranges for the amount of co Q10 dissolved in the limonene and the additional ingredients in the solution (rice brain oil, beeswax, a tocopherol, fish oil, an antioxidant) are the same in each case, or are overlapping for the ranges, and do not create separate inventions. Therefore, these inventions are not patentably distinct.

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Claims 14, 15, 18-20, 22, 23, 32-34, 36-43 and 45-55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 7,273,606. Similarly to the above rejection, although the conflicting claims are not identical, they are not patentably distinct from each other because each claim set is drawn to the same invention, a composition or nutraceutical formulation that is a soft gel capsule comprising a solution of co Q10 dissolved in limonene. The instant claims are broader than the patented claims, because the patented claims recite that the composition comprises carnitine as well. But, the instant specification discloses that the composition may further comprise carnitine as an additional therapeutic ingredient. See paragraphs 35 and 36. The additional limitations recited in the instant and in the patented claims, the concentration ranges for the amount of co Q10 dissolved in the limonene and the additional ingredients in the solution (rice brain oil, beeswax, a tocopherol, an antioxidant) are the same in each case, or are overlapping for the ranges, and do not create separate inventions. Therefore, these inventions are not patentably distinct.

Claims 14, 15, 18-20, 22, 23, 32-34, 36-43 and 45-55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 7,713,523. Similarly to the above rejections, although the conflicting claims are not identical, they are not patentably distinct from each other because each claim set is drawn to the same invention, a composition or nutraceutical formulation comprising a solution of co Q10 dissolved in limonene. The instant claims are broader than the patented claims, because the patented claims recite that the composition comprises carnitine as well. But, the instant specification discloses that the composition may further comprise carnitine as an additional therapeutic ingredient. See paragraphs 35 and 36. The patented claims do not recite that the composition has the form of a soft gel capsule, but the solution and the soft gel were not

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restricted apart in this case. The patented specification discloses that the composition is in the form of a soft gel (see paragraphs 14, 16, 20, 37, 49-59 and Examples 1 and 2). The additional limitations recited in the instant and in the patented claims, the concentration ranges for the amount of co Q10 dissolved in the limonene and the additional ingredients in the solution (rice brain oil, beeswax, a tocopherol, an antioxidant) are the same in each case, or are overlapping for the ranges, and do not create separate inventions. Therefore, these inventions are not patentably distinct.

Claims 14, 15, 18-20, 22, 23, 32-34, 36-43 and 45-55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 10/953328. Although the conflicting claims are not identical, they are not patentably distinct from each other because each claim set is drawn to the same invention, a composition or nutraceutical formulation that is a capsule comprising a solution of co Q10 dissolved in limonene. The copending claim is broader than the instant claims, because the copending claim does not recite a concentration range for the amount of co Q10 in the composition. But, the ranges and the additional ingredients recited in the instant claims do not create separate inventions. Therefore, these inventions are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROSANNE KOSSON whose telephone number is (571)272-2923. The examiner can normally be reached on Mon., Thurs., Fri., 8:30-6:00, Tues., 8:30-2:00, Wed. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rosanne Kosson/
Primary Examiner, Art Unit 1652
2011-06-30